## REMARKS

Upon entry of the amendment, claims 8, 9, 11 to 17 and 24 to 34 will be pending.

Claim 8 has been amended to recite "an autoimmune disease or graft rejection" support being provided, for example, at page 5, lines 13-16, and page 9, lines 19-24(see, also, original claim 10). Claim 8 also has been amended to more correct an informality, wherein no antecedent basis was provided for recitation of the term "the patient".

New claims 25 to 34 have been added. New claims 25 to 28 are supported by original claims 9, 11, 15 and 16, respectively. New claim 29 is supported, for example, at page 5, lines 13-16, and page 9, lines 19-25 (see, also, original claim 10). New claims 30 to 33 are supported by original claims 9, 11, 13, and 16, respectively. New claim 34 is supported, for example, at page 10, lines 3-5. As such, new claims 25 to 34 do not add new matter.

### A. Rejection Under 35 U.S.C. 112, First Paragraph (Enablement)

The rejection of claim 24 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is respectfully traversed.

Applicants maintain that the specification teaches one skilled in the art how to ameliorate an immune response mediated disorder selected from AIDS, autoimmune disease, and graft rejection. It is alleged in the Advisory Action there the application provides no working examples that meet the claimed limitations. However, the specification discloses that antibodies encompassed within the claimed methods can inhibit HIV-mediated syncytium formation is culture (see, e.g., page 21, line 18, to page 22, line 20; and page 24, lines 11-15). Thus, the specification discloses that a means by which HIV can spread among cells in a subject is

prevented using such antibodies. As such, it is submitted, the skilled artisan, viewing such evidence, reasonably would have known that such an effect also can occur in an animal because it is well known that effects observed due to antibodies *in vitro* similarly can occur *in vivo* as evidenced by well known and routinely used passive immunization methods.

It is also stated in the Advisory Action that the art describes a number of failures regarding immunotherapy of HIV. However, the art similarly describes clinical trials relating to such immunotherapy (see Exhibits A to C submitted with Applicants' previous Amendment). It is submitted that such on-going trials provide objective evidence that those skilled in the art believe that immunotherapy can be useful for treating HIV infection. It is further noted that the Exhibits A to C, which include Phase I (Exhibit B) and Phase III (Exhibit C) clinical trials using passive immunization methods for treating HIV, were submitted only as evidence that the application as filed, which discloses the use of passive immunization to ameliorate the recited disorders, was enabling at the time of filing.

It is also stated in the Advisory Action that the specification does not provide a description as to how such antibodies should be administered, or what clinical changes or benefits are to result. It is submitted, however, that factors relating to the administration of the antibodies is the subject of clinical trials, as is known in the art, and that the skilled clinician would know measures of clinical benefit typically used for monitoring the particular recited disorders.

For the above reasons, Applicants maintain that one skilled in the art, viewing the subject application, would have known how to practice the claimed methods without undue experimentation. Accordingly, reconsideration and removal of the rejection under 35 U.S.C. § 112, first paragraph, are respectfully requested.

**B. Prior Art Rejections**

The rejections of the claims under 35 U.S.C. § 102(e) as allegedly being anticipated by Arfors and under 35 U.S.C. § 102(b) as allegedly being anticipated by Vedder et. al are respectfully traversed.

The rejections are based on the Examiner's position that "an immune response mediated disorder" encompasses an immune response that occurs due to necrosis that can occur to ischemia/reperfusion induced tissue damage. Although Applicants maintain, for reasons of record, that one of ordinary skill would not understand such ischemia/reperfusion induced damage and subsequent inflammatory response to be "an immune response mediated disorder", it is nevertheless noted that the amended claims recite specific disorders, none of which is taught or suggested by the cited references, either alone or in combination. Accordingly, it is respectfully requested that the rejections of the claims under 35 U.S.C. 102(e) and/or 35 U.S.C. 102(b) be removed.

The rejections of the claims under 35 U.S.C. 103(a) as allegedly being unpatentable over Arfors and Vedder et al. in view of Springer et. al., and under 35 U.S.C. § 103(a) as allegedly being unpatentable over Arfors, Vedder, et. al., and Springer, et. al., in view of Hildreth, et. al., are respectfully traversed.

In view of the amendments to the claims, it is submitted that Arfors and Vedder et al. are not relevant because neither reference teaches or suggests ameliorating AIDS, an autoimmune disease, or graft rejection. As such, one of ordinary skill in the art would not have considered Arfors or Vedder et al. or, therefore, have had any motivation to combine either reference with Springer et al. As such, it is submitted that the rejection should be removed for this reason.

Even if, however, it is assumed for argument sake that Arfors and/or Vedder et al. are relevant to the claimed invention, Applicants maintain that Springer et al. do not describe the use of antibodies for treating an immune response mediated disorder such as allograft rejections.

Springer et al. generally describe antibodies specific for LAC components and the use of such antibodies for diagnostic purposes, but do not teach or suggest the use of such antibodies to ameliorate an immune response mediated disorder. However, Springer et al. only describe the use of the polypeptide components of LAC (e.g., LFA-1), including peptides thereof, to treat an immune disorder (see page 12). As such, Springer et al. do not provide that which is missing in the Arfors and Vedder et al. references.

Similarly to above, and further with respect to the Hildreth et al. reference, it is submitted that Hildreth et al. do not provide that which is missing in the absence of Arfors and Vedder et al. and, even if considered with those references and Springer et al., would not have rendered the claimed methods obvious. Accordingly, it is respectfully requested that the rejections of the claims under 35 U.S.C. 103(a) be removed.

**C. Double Patenting Rejection**

Claims 8 to 17 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1 to 7 of U.S. Patent No. 5,888,508. Applicant acknowledges the rejection and will file a Terminal Disclaimer, disclaiming any term of a patent issuing from the subject application that may extend beyond the term of U.S. Patent No. 5,888,508, upon receiving an indication that the present claims otherwise are in condition for allowance.

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect respectfully is requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

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